RVD2008-10

Re-evaluation Decision

Sethoxydim

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Overview

Re-evaluation Decision

After a re-evaluation of the herbicide sethoxydim, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing sethoxydim.

An evaluation of available scientific information found that products containing sethoxydim do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of sethoxydim uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of sethoxydim was first presented in Proposed Re-evaluation Document PRVD2007-17, *Re-evaluation of Sethoxydim*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of sethoxydim, the Agency's decision and the reasons for it. No comments were received during the consultation process. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2007-17. To comply with this decision, registrants of products containing sethoxydim will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Sethoxydim, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA is taking a regulatory decision and is requiring appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated sethoxydim and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation of the related Proposed Re-evaluation Decision PRVD2007-17, *Re-evaluation of Sethoxydim*.

What Is Sethoxydim?

Sethoxydim is a herbicide used to control weeds on many food and feed crops and on creeping red fescue for seed production, on flax for industrial and fibre production, on shelter belts of chokecherry and on ornamental trees and shrubs. Sethoxydim is applied using ground or aerial equipment by farm workers and professional applicators as well as by homeowners.

Health Considerations

Can Approved Uses of Sethoxydim Affect Human Health?

Additional risk-reduction measures are required on sethoxydim labels. Sethoxydim is unlikely to affect your health when used according to revised label directions.

Exposure to sethoxydim may occur through food and water, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that sethoxydim was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions were considered applicable to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Sethoxydim is currently registered in Canada for use on asparagus, carrots, potatoes, sweet potatoes, sugar beets, turnip, Chinese radish, garlic, onion, spinach, mustard greens, broccoli, cabbage, cauliflower, Chinese broccoli, napa cabbage, kohlrabi, mustard cabbage, beans, soybeans, lentils, peas, snow peas, chickpeas, tomatoes, peppers, cucumbers, pumpkins, squash, bearing and non-bearing fruit trees, highbush blueberries, raspberries, cranberries, strawberries, buckwheat, mint, caraway, dill, coriander, mustard seed, canola/rapeseed, safflower, flax, sunflowers, hops and forage legumes.

Sethoxydim may be used in other countries on other crops imported into Canada. Where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm, which is considered a general MRL for enforcement purposes.

MRLs for sethoxydim are established for the following commodities: lentils at 30 ppm; tomato paste at 15 ppm; dry beans, peas and strawberries at 10 ppm; sunflowers at 7 ppm; beans, raspberries and soybeans at 5 ppm; blueberries, potatoes and tomatoes at 4 ppm; artichokes, cabbage, cantaloupes, cranberries, eggplants, eggs, mustard, mustard greens and spinach at 2 ppm; celery, cucumbers, lettuce, pumpkins and squash at 1 ppm; asparagus, broccoli, corn, peppers and poultry liver at 0.5 ppm; flax, onions, poultry meat and turnips at 0.2 ppm; and carrots at 0.1 ppm.

Changes to the general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

Environmental Considerations

What Happens When Sethoxydim Is Introduced Into the Environment?

Additional risk-reduction measures are required on sethoxydim labels. Sethoxydim is unlikely to affect non-target organisms when used according to revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to sethoxydim in the environment. Environmental risk is assessed by the risk quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting RQs are compared to corresponding levels of concern (LOCs). An RQ less than the LOC is considered a negligible risk to non-target organisms, whereas an RQ greater than the LOC indicates some degree of risk.

The USEPA concluded that the reregistration of sethoxydim was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions were considered applicable to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require aquatic and terrestrial buffer zones for sethoxydim to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Registered pesticide product labels contain specific directions for use, which include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of sethoxydim, further risk-reduction measures are proposed in addition to those already identified on existing sethoxydim product labels. These additional measures are designed to further protect human health and the environment, and are summarized as follows:

Human Health

- To protect workers re-entering treated sites: restricted-entry interval

Environment

- To reduce potential surface and groundwater contamination: additional advisory label statements
- To protect non-target sensitive species: buffer zones for aquatic and terrestrial habitats

Appendix I lists all required label amendments, including instructions related to basic hygiene practices.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter.

Appendix II lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on sethoxydim within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Sethoxydim

Canadian end-use product labels must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

- DO NOT apply this product in a way that will cause this product to contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application.

- DO NOT enter or allow entry into treated areas during the restricted-entry interval (REI) of 12 hours.

II) The following statements must be included in the **DIRECTIONS FOR USE** section:

- Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers medium classification.

- When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

III) The following statements must be included in the **DIRECTIONS FOR USE** section of the end-use product Registration Number 25820 label:

- DO NOT apply by air.

- **Buffer zones:** The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands).

Method of Application	Buffer Zones (metres) Required for the Protection of Terrestrial Habitats
Field sprayer	1

IV) The following statements must be included in the **DIRECTIONS FOR USE** section of the end-use product Registration Number 24835 label:

- Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers medium classification. DO NOT allow nozzle spacing to exceed 65% of boom length.

- **Buffer zones:** The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	**Crop**		**Buffer Zones (metres) Required for the Protection of:**		
			Aquatic Habitats of Depths:		**Terrestrial Habitats**
			Less than 1 m	**Greater than 1 m**	
Field sprayer	All crops		0	0	1
Aerial	Food/feed crops	Fixed wing	0	0	60
		Rotary wing	0	0	50
	Non-croplands, orchards, ornamental trees, shelter belts	Fixed wing	55	0	200
		Rotary wing	40	0	150

V) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

- TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

- This product contains a petroleum distillate that is moderately to highly toxic to aquatic organisms. Avoid contamination of aquatic systems during application.

- DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuaries or marine habitats.

- DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

- To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to, heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay).

- Avoid application of this product when heavy rain is forecast.

- Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

Appendix II Additional Data Requirements

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter:

- DACO 9.3.5 – Non-target freshwater invertebrates - Laboratory studies with end-use product; chronic (life cycle) test with *Daphnia* sp.

- DACO 9.5.4 – Fish - Laboratory studies with end-use product; fish early life stage toxicity test conducted with rainbow trout.

- DACO 9.8.6 – Non-target plants - Laboratory studies with end-use product; Tier II vegetative vigour and seedling emergence studies and Tier II aquatic vascular studies.

These studies must be conducted with a Canadian end-use product or a product with equivalent formulation and guarantee and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organisation for Economic Co-operation and Development guidelines. Should the registrant fail to submit these studies within the specified timeline, in place of the interim buffer zones, conservative buffer zones for the protection of sensitive terrestrial and aquatic habitats will be required on product labels.